



Memorandum

Date March 27, 2024

From Sherry Xu
IRB Reviewer, NIOSH Institutional Review Board

Subject NIOSH IRB Conditional Approval Report for 23-NIOSH-12, “Assessment of task-based exposures that may affect reproductive health in nail salon employees”

To Paro Sen
Project Officer, FRB, DFSE
Through: /Branch Official, FRB, DFSE _____
/Division Official, DFSE _____

General Comments and IRB Actions

This protocol was reviewed by a member of the NIOSH IRB using the expedited procedure because it meets the CDC conditions for expedited review. The research presents no greater than minimal risk to subjects and involves only procedures listed in the expedited review categories 1-7 referenced in 45 CFR 46.110. Approval of your study is conditioned on your satisfactory response to the issues raised in this Report.

Please respond only to issues raised in this report. Any protocol changes accompanying your response must pertain to an issue raised in this report. Please advise the IRB if you wish to make any protocol changes independent of this report, as they may require separate IRB review and approval prior to implementation.

Protocol Issues

1. Section 7.3. Protocol Amendment History table should be left blank since the current updates of the protocol are part of the initial review not an amendment.

Please prepare your Response by entering your responses into this request, and changing the “to,” “from” and “date” headings. Please sign below and obtain DLO leadership approval and initials on the first page of this report.

Please respond only to issues raised in this report. Any protocol changes accompanying your response must pertain to an issue raised in this report. Please advise the IRB if you wish to make any protocol changes independent of this report, as they may require separate IRB review and approval prior to implementation.

Please email the following documents to the NIOSH IRB (cin-hsrp@cdc.gov) with subject heading “23-NIOSH-12 PI Response to NIOSH IRB Conditional Approval Report”:

- 1) A PDF or word document of your Response
- 2) A PDF or word document of the Clean Protocol
- 3) A PDF or word document of the Revised Tracked Protocol
- 4) The Form 0.1255 (the original or a new form if information has changed)

End of Report